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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,507

06/27/2003

Han Cui

ETH-5071

9283

27777

7590

07/03/2006

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,507	CUI ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 - 8, 11 - 22 and 25 - 29 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 23 and 24 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12-7-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt of Applicants' Response to Election/Restriction requirement, filed 5/2/2006, is acknowledged. Applicant elected the species of a poly(monostearoyl glycerol-co-succinate) as the second and third biodegradable polymers, and further noted that claims 10 and 24 read on the elected species. Claims 6 and 20, which require the second and third biodegradable polymer to be different, do not read on the elected species and are therefore withdrawn as reading on a non-elected species of the invention.

Allowable Subject Matter

The elected species is deemed to be free of the prior art. As such, the search was extended to encompass the non-elected species of the invention. Claims 9, 10, 23, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and, in the case of claim 10, corrected for the minor informalities discussed below.

Claim Objections

Claims 7, 8, 10, 21, and 24 are objected to because of the following informalities: Claims 7 and 21 each require a closing parenthesis after the word "anhydrides". Claim 8 ends with two periods, one of which must be deleted. Claims 10 and 24 each require a closing parenthesis after the word "succinate". Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 8, 11 – 22 and 25 - 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,891,223 to Ambeganokar et al.

The '223 reference discloses microparticles that comprise a core, containing a drug, and two coatings disposed thereon (figure, abstract). The first coating comprises a water soluble polymer, such as HPMC, and the second coat comprises a water-insoluble polymer, such as ethyl cellulose, and the core comprises two polymers, HPMC, which is the same as the polymer of the first coat, and starch, which is different from the polymer of the first coat (example 5, see also col. 6 line 42 – col. 7 line 25). The amount of drug in the core is commensurate with the requirements of instant claims. The microparticles are disclosed to be as small as 125 microns (col. 7, lines 3 – 9), and as such are perinterally administratable. Furthermore, the particles are disclosed to be placed water at a pH of 7 (example 5), which is a biocompatible carrier suitable for the microparticle.

Conclusion

No claims are allowed. Claims 1 – 8, 11 – 22 and 25 - 29 are rejected, and claims 7, 8, 10, 21, and 24 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1615



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